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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/863,824 | 05/23/2001 | C. Alexander Turner JR. | LEX-0181-USA | 8987 |

24231 7590 12/03/2002

LEXICON GENETICS INCORPORATED
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THE WOODLANDS, TX 77381-1160

EXAMINER

RAMIREZ, DELIA M

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1652

DATE MAILED: 12/03/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/863,824

Applicant(s)

TURNER ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002 .
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-7 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

DETAILED ACTION

Status of the Application

Claims 2-7 are pending.

Applicant's amendment of claim 2, cancellation of claim 1 and addition of claims 6-7 in Paper No. 12, filed on 9/19/2002 is acknowledged.

This application contains claims 4-5 drawn to an invention non-elected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. It is noted that while Applicants have stated in the Response that claims 4-5 have been cancelled, a request for cancellation has only been made for claim 1 (see first 3 lines of the Amendment).

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 2-3, 6-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.

3. Claims 2-3, 6-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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4. These rejections, which were discussed in previous Office Actions Paper No. 10, mailed on 5/14/2001, were applied to claims 2-3 and are now applied to new claims 6-7 for the reasons of record.

5. Applicants have extensively argue that the polynucleotides of the instant invention have substantial, credible, specific and well-established utility. Applicants assert that the utility of the polynucleotide of the present invention relates to polymorphisms and that polymorphisms have significant and specific utility in the area of forensics and human population biology. In addition the polymorphisms of the present invention can have utility in resolving issues of paternity. In view of all these uses, the claimed invention undoubtedly has "real world" use. In addition, an additional utility for the claimed polynucleotides is in the manufacture of DNA chips as evidenced by hundreds of issued patents. Since the present nucleotides are specific markers of the human genome, one can use them in the discovery of drugs or in screening for gene expression. Furthermore, Applicants argue that the present nucleotides have a specific utility in mapping the protein encoding regions of human chromosome 20 and in expanding the value of the data coming from the human genome project. Applicants assert that while some aspects of the invention may required further research, it is not "undue experimentation" as stated in *In re Brana*. It is Applicant's opinion that the PTO has issued several patents on polynucleotides that have not been directly associated with the function of the polypeptide they encode. Finally, Applicants direct the Examiner's attention to several patents where there are no working examples or examples of real-world utilities.

6. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the utility rejection. As indicated in previous Office Action Paper No. 10, the

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polynucleotide of SEQ ID NO: 1 has been disclosed as being a thrombospondin however the closest homolog found is a serine palmitoyltransferase having 36.8% sequence identity to the polypeptide encoded by the polynucleotide of SEQ ID NO: 1 and the closest thrombospondin homolog is 5% sequence identical to the polypeptide encoded by the polynucleotide of SEQ ID NO: 1. Therefore, it appears that there is no evidence to clearly support Applicant's assertion in regard to function. Furthermore, Applicants have not disclosed which type of thrombospondin is encoded by the polynucleotide of SEQ ID NO: 1 since it is known in the art that these proteins belong to a family of at least 5 members in vertebrates, each with diverse function. As such, there is no specific utility for the polynucleotide encoding the polypeptide of SEQ ID NO: 2.

While it is agreed that a polynucleotide can be used in the fields of forensics, human biology, or paternity determination, these are not specific uses. In regard to arguments that the instant polynucleotide can be used in DNA chips, drug discovery, and mapping, those uses are not "substantial" in view of the further research required to identify or reasonably confirm a "real world" context of use. It is noted that, contrary to Applicant's opinion, the instant utility rejection is not made in view of lack of FDA approval or on the basis of "additional research" alone but rather due to the fact that the actual function of the polynucleotide claimed is unknown. Even if Applicant's assertion of function is correct, there is no disclosure of its role in humans or how the underexpression or overexpression of such polynucleotide correlates with a disease or an abnormality. Without this information, it is unclear how one of skill in the art can reasonably use this polynucleotide in drug discovery.

In regard to specific utility in mapping the protein encoding regions of human chromosome 20, it is noted that if the function of the target polynucleotide is unknown, there is

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no specific utility for the polynucleotide of the instant invention as a probe. In response to arguments that the PTO has issued several patents on polynucleotides which do not have a specific function associated with them or patents which lack real-world utility or working examples, Applicants are reminded that each application is examined on its own merits and that the instant application is being examined using the revised utility guidelines.

7. In case Applicant overcomes this utility rejection by providing convincing evidence in response to this Office Action, the following rejections will apply:

Claim Rejections - 35 USC § 112, Second Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 2 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. This rejection has been discussed in previous Office Action Paper No. 10, mailed on 5/14/2002.

11. Applicants argue that the amendments to claim 2 should be sufficient to overcome the rejection.

12. Applicants have amended the claim which now recites “complete complement” and states specific wash conditions for the hybridization reaction. However, the claim is still indefinite in the recitation of “an isolated nucleic acid molecule comprising a nucleotide sequence that: (b)

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hybridizesto the nucleotide sequence of SEQ ID NO: 1” since, as indicated previously, hybridization occurs only among molecules and not among sequences. Correction is required.

Conclusion

13. No claim is in condition for allowance.

14. Applicant's amendment of claim 2 and addition of claims 6-7 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

16. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with

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the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
November 27, 2002


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1602